

CLAIMS

What is claimed is:

5 1. A recombinant Helicobacter pylori protein, or a derivative or fragment thereof.

10 2. The recombinant protein according to claim 1 wherein the protein is a Helicobacter pylori cytotoxin or a precursor, derivative or fragment thereof.

15 3. The recombinant protein according to claim 2 wherein the cytotoxin, precursor, derivative or fragment thereof has the amino acid sequence of Figure 2, or a portion thereof.

20 4. The recombinant protein according to claim 1 wherein the protein is a Helicobacter pylori cytotoxin associated immunodominant antigen, or a derivative or fragment thereof.

25 5. The recombinant protein according to claim 4 wherein the cytotoxin associated immunodominant antigen, derivative or fragment has the amino acid sequence of Figure 4, or a portion thereof.

30 6. The recombinant protein according to claim 1 wherein the protein is a Helicobacter pylori heat shock protein, or a derivative or fragment thereof.

35 7. The recombinant protein according to claim 6, wherein the heat shock protein, derivative or fragment has the amino acid sequence of Figure 5 or a portion thereof.

8. The recombinant protein according to claim 2 or 3 wherein the recombinant protein exhibits substantially no toxicity, or substantially reduced toxicity.

9. The recombinant protein according to any one of claims 4 to 7 wherein the recombinant protein is

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immunogen₃ and exhibits no functional contribution to toxicity, or a substantially reduced functional contribution to toxicity.

5 10. The recombinant protein according to claim 8 or 9 wherein the recombinant protein is chemically modified to reduce or abolish toxicity or functional contribution to toxicity.

10 11. The recombinant protein according to claim 8 or 9 wherein the recombinant protein contains one or more amino acid substitutions or deletions.

15 12. The recombinant protein according to any one of the preceding claims which is labelled or coupled to a solid support.

20 13. The recombinant protein according to any one of claims 1 to 11 for use in the treatment of Helicobacter pylori infection.

14. The recombinant protein according to any one of claims 1 to 11 for use as a vaccine.

25 15. A vaccine or therapeutic composition comprising a recombinant protein according to any one of claims 1 to 11 and a pharmaceutically acceptable carrier.

30 16. The vaccine or therapeutic composition according to claim 15 comprising two or more recombinant proteins according to any one claims 1 to 11.

35 17. The vaccine or therapeutic composition according to claim 16 comprising, in combination, two or more of

i) a recombinant Helicobacter pylori cytotoxic protein precursor, derivative or fragment thereof,

ii) a Helicobacter pylori recombinant cytotoxin

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associated immunodominant antigen, or a derivative or fragment thereof;

iii) Helicobacter pylori recombinant heat shock protein or a derivative or fragment thereof and/or

5 iv) a Helicobacter pylori urease.

18. The vaccine or therapeutic composition according to any one of claims 15 to 17 comprising an adjuvant.

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19. A method for the preparation of a vaccine or therapeutic composition according to any one of claims 15 or 18 comprising bringing one or more recombinant proteins according to any one of claims 1 to 11 into association with
15 a pharmaceutically acceptable carrier and optionally an adjuvant.

20. An immunodiagnostic assay comprising at least one step involving as at least one binding partner, a recombinant protein according to any one of claims 1 to 12,
20 optionally labelled or coupled to a solid support.

21. An immunodiagnosis kit for performing an assay according to claim 20, comprising at least one
25 recombinant protein according to any one of claims 1 to 20.

22. Use of one or more recombinant proteins according to any one of claims 1 to 11 for the manufacture of a medicament for the treatment of Helicobacter pylori
30 infection.

23. A method of treatment of an individual infected with Helicobacter pylori comprising administering an effective amount of a recombinant protein according to 1
35 to 11.

24. The method of treatment according to claim 23 comprising administering an effective amount of, in combination, two or more of

i) a recombinant Helicobacter pylori cytotoxic protein precursor, derivative or fragment thereof,

ii) a Helicobacter pylori recombinant cytotoxin associated immunodominant antigen, or a derivative or
5 fragment thereof,

iii) a Helicobacter pylori recombinant heat shock protein or a derivative or fragment thereof and/or

iv) a Helicobacter pylori urease.

10 25. A method of vaccination comprising administering an immunologically effective amount of, in combination, two or more of

i) a recombinant Helicobacter pylori cytotoxic protein precursor, derivative or fragment thereof,

15 ii) a Helicobacter pylori recombinant cytotoxin associated immunodominant antigen, or a derivative or fragment thereof,

iii) a Helicobacter pylori recombinant heat shock
20 protein or a derivative or fragment thereof and/or

iv) a Helicobacter pylori urease.

26. A recombinant polynucleotide encoding a recombinant protein according to any one of claims 1 to 11.

25 27. A recombinant polynucleotide encoding a Helicobacter pylori cytotoxic protein or a derivative or fragment thereof comprising all or part of the nucleotide sequence of Figure 1.

30 28. A recombinant polynucleotide encoding a Helicobacter pylori recombinant cytotoxin associated immunodominant antigen or a derivative or fragment thereof comprising all or a part of the nucleotide sequence of
35 Figure 4.

29. A recombinant polynucleotide encoding a Helicobacter pylori recombinant heat shock protein or a derivative or fragment thereof comprising all or a part of

the nucleotide sequence of Figure 5.

5 30. A polynucleotide probe comprising all or part of the recombinant polynucleotide according to any one of claims 26 to 29.

 31. A nucleic acid assay wherein in at least one step involves a polynucleotide probe according to claim 30.

10 32. A kit for performing a nucleic acid assay comprising at least one polynucleotide probe according to claim 30.

15 33. A polynucleotide amplification process employing a polynucleotide primer wherein in at least one primer is a recombinant polynucleotide comprising all or part of the recombinant polynucleotide according to any one of claims 26 to 29.

20 34. A kit for performing a polynucleotide amplification process employing a polynucleotide primer wherein in at least one primer is a recombinant polynucleotide comprising all or part of the recombinant polynucleotide according to any one of claims 26 to 29.

25 35. A vector comprising a recombinant polynucleotide according to any one of claims 26 to 29.

30 36. A host cell transformed with a vector according to claim 35.

35 37. A method for the production of a recombinant polypeptide according to any one of claims 1 to 11, comprising culturing a host cell according to claim 36 and isolating the recombinant polypeptide.